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Attorney Docket No.: 0788.00063

## **REMARKS**

Claims 7 and 8 are currently pending in the application. Only claim 7 is in independent form.

Applicants wish to express their appreciation for the courtesies extended Applicants' representative, Amy E. Rinaldo, during a telephonic interview conducted on October 11, 2006.

Claims 7 and 8 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention.

The Office Action has held that claim 7 is unclear as to what is intended. Specifically, the Office Action questions what was intended by "based upon reactivity" in claim 7. During the telephonic interview the phrase was discussed and alternative claim language was agreed upon, such language has been incorporated in the present amendment. Claim 7 has been amended to remove the language, and reconsideration of the rejection is respectfully requested.

Claims 7 and 8 stand rejected under 35 U.S.C. §102(a) as being anticipated by the Sioud et al., reference. Reconsideration of the rejection under 35 U.S.C. §102(a), as anticipated by the Sioud et al., reference, as applied to the claims is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

In <u>Hybritech Inc. v. Monoclonal Antibodies, Inc.</u>, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986) it was stated: "For prior art to anticipate under §102 it has to meet every element of the claimed invention."

In <u>Richardson v. Suzuki Motor Co., Ltd.</u>, 868 F.2d 1226, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989) it was stated: "Every element of the claimed invention must be literally present, arranged as in the claim."

The Office Action has held that the Sioud et al., reference discloses an analysis of the humoral response in patients with cancer. Libraries from breast cancer cell lines were biopanned and positive clones were selected. Using serum antibodies

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from patients with breast cancer, IgG-binding phage-encoded cDNA products were selected and the clones identified important antigens. The Office Action has held that the disclosure is identical to the presently pending independent claims. However, when read more specifically, the Sioud et al., reference discloses at page 718, that

"...further rounds of selection should, in principle enrich for the best binders. If the selection is specific an increase in the number of positive clones is likely. In this respect, after three rounds of selection on patient IgG positive clones were selected."

In other words, the Sioud et al., reference teaches that in order to obtain the desired markers the screening should become more and more specific.

It is well known to biopan for a specific composition, as is disclosed in the Sioud et al., reference. However, there is no disclosure assay currently available that will screen or create an array of markers that are accurate in diagnosing and staging cancer or other forms of disease. In other words, while the Sioud et al., reference discloses biopanning methods that can determine the presence of a single marker, there is no disclosure for a method or assay that will simultaneously screen for an unlimited number of markers within sera. The reference only teaches obtaining approximately 5-10 markers. This is a low throughput method. In contradistinction, the present claimed invention instead recites a high throughput method that creates more robust results. The presently pending claim recites a method for detecting sets of markers of disease. The purpose of the method is to use differential biopanning of normal patients and patients having the disease against a phage library in order to determine which markers are present in the disease state but are not present in the normal state. It is the limitless number of markers that are then used to create an array against which individuals suspected of having disease can be tested. This is not known or disclosed or suggested by any of the cited prior art. By way of comparison, the invention as recited in the presently pending independent claims provides a more robust and high throughput tool that can provides an improved technology for the use in detecting markers that is similar in the robustness provided by a microarray versus between a Northern blot. Since the Sioud et al., reference does not disclose the

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method of the presently pending independent claim, the claim is patentable over the Sioud et al., reference and reconsideration of the rejection is respectfully requested.

It is respectfully requested that the present amendment be entered in order to place the application in condition for allowance or at least in better condition for appeal. The application is placed in condition for allowance as it addresses and resolves each and every issue that remains pending. The amendments overcoming the rejections under 35 U.S.C. §112 are made exactly as suggested by the Office Action. Claims have also been amended to clearly distinguish over the prior art. The application is made at least in better condition for appeal as the amendment removes many issues thereby simplifying the issues on appeal. That is, each and every rejection under 35 U.S.C. §112 has been overcome exactly as suggest in the Office Action. Further, the claims have been amended to more specifically define the invention while raising no new issues that would require any further searching. Rather, the amendments have been made in view of comments made in the Office Action that clearly distinguish the presently pending claims over the cited prior art. Hence, it is respectfully requested that the amendment be entered.

This amendment could not have been made earlier as the amendment further defines the claims over the prior art in accordance with the suggestion made in the Office Action, the suggestion first being made in the outstanding Office Action. Hence, since there remain no further issues to be resolved, it is respectfully requested that the present amendment be entered.

The remaining dependent claim not specifically discussed herein is ultimately dependent upon the independent claim. The reference as applied against the dependent claim does not make up for the deficiencies of the reference as discussed above. The prior art reference does not disclose the characterizing features of the independent claim discussed above. Hence, it is respectfully submitted that both of the pending claims are patentable over the prior art.

In conclusion, it is respectfully requested that the present amendment be entered in order to place the application in condition for allowance, which allowance is respectfully requested.

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If any remaining issues exist, Applicants respectfully request to be contacted by telephone at (248) 539-5050.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

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Dated: October 25, 2006

## **CERTIFICATE OF MAILING BY "EXPRESS MAIL"**

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Connie Herty